

K092833

510(k) Summary

Submission Date: September 8, 2009

Submitter's Information:

Dentamerica Inc.®
18688 E. San Jose Ave.
Industry, CA 91748 USA

Contact Person: Eric Huang, (Product Manager)
Phone: 626-912-1388
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Establishment Registration Number: 2024949

Trade Name: Endomax™

Common Name: Cordless Endodontic Handpiece

Regulation Number: 21 CFR 872.4200

Regulation Name: Handpiece, Direct Drive, AC-powered

Regulatory Class: Class I

Product Code: EKX

Performance Standard: None established under section 514

Reason for 510(k): New finished device

Special controls: No applicable mandatory performance standards or special controls exist for this device.

Substantially Equivalent Legally Marketed Devices (predicates):

ENDO-MATE TC Cordless Handpiece – K990682

Tri Auto ZX Cordless Endodontic Handpiece – K970339

Indications for Use:

The Endomax™ is a cordless handpiece used primarily for root canal enlargement. This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.

Technological Characteristics and Substantial Equivalence:

The Endomax™ Cordless Endodontic Handpiece has a number of substantially equivalent (SE) predicate devices. These predicate devices use the same technological methods to perform mechanical and rotary preparation of root canals with a cordless handpiece. A modular electrical system consisting of a drive handpiece, a rechargeable battery, contra-angle head and a charging station are the main components of the predicate devices. The materials used in this device are composed of brass, silicon and Type II plastic as in the substantially equivalent devices.

The cordless endodontic handpiece introduces the convenience of portable operation without a cumbersome cord. The benefits of this can be demonstrated clinically. First, a cordless handpiece offers greater control and flexibility. In addition, cordless endodontic handpieces offer automatic functions such auto start/stop and auto torque reverse, enabling the clinician to perform safer and more accurate endodontic treatment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mr. Eric Huang
Manager
Dentamerica
18688 East San Jose Avenue
Industry, California 91748

JAN - 7 2010

Re: K092833
Trade/Device Name: Endomax Cordless Endodontic Handpiece
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: December 14, 2009
Received: December 23, 2009

Dear Mr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, BS, MS, MBA

Director

Division of Anesthesiology, General Hospital,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092833

Device Name: Endomax™ Cordless Endodontic Handpiece

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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